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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,945	05/14/2001	Clifton A. Alferness	1931-2	1454

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EXAMINER

CHATTOPADHYAY, URM

ART UNIT	PAPER NUMBER
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3738

20

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,945

Applicant(s)

ALFERNESS ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-15,41,42 and 44-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-15,41,42,44-65,67-69,71 and 72 is/are rejected.
- 7) ☒ Claim(s) 66,70 and 73 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 19.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Request for Continued Examination

1. The request filed on 1/16/04 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 09/855,945 is acceptable and a RCE has been established. An action on the RCE follows.

Response to Amendment

2. The amendment filed 1/16/04 has been entered as Paper No. 18. All pending claims, claims 1, 2, 4-15, 41, 42 and 44-73, are being considered for further examination on the merits.

Information Disclosure Statement

3. The Information Disclosure Statement filed 1/16/04 has been entered as Paper No. 19. The references that are not initialed and have a line drawn through them were previously considered and cited by the examiner in PTO-892s filed with the office actions mailed 12/20/02 and 6/5/03. In order to prevent duplication of the citations, they have not been considered again.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 4-7, 9-11, 15, 41, 44-47, 49-51, 55-62, 64, 65, 67- 69, 71 and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Langberg et al. (USPN 6,402,781 as cited in previous office action).

Langberg et al. discloses an assembly for effecting the condition of a mitral valve annulus and a mitral valve annulus constricting or therapy device with all the elements of claims 1, 41, 56 and 57. See column 10, lines 40-44 for a guide wire configured to be fed into the coronary sinus of the heart and a mitral valve annulus device (66) configured to be slidably received on the guide wire and advanced into the coronary sinus of the heart on the guide wire and that reshapes the mitral valve annulus when in the coronary sinus of the heart (see abstract). The guide wire lumen that extends from one end of the device to an opposing end forms a guide wire engaging structure at at least one of the ends thereof. See column 8, lines 40-43 for the mitral valve annulus device having a nitinol metal ribbon (58), thereby rendering the device resilient and configured to be deformed so that it is capable of being slidably received on the guide wire. Because the nitinol ribbon influences the plane of curvature of the device so that the device will tend to curve towards the direction of the mitral valve annulus, axial manipulation of forming element (56) will further arch the device to exert a substantially radially inward force on the mitral valve annulus. For claims 56 and 57, see Figure 2 for device having an arched configuration and being a generally C-shaped member.

Claims 4-7, 44-47 and 58-61, see column 10, lines 40-44. The lumen, which is inherently cylindrical in shape, defines bores at each of the ends of the device, which are dimensioned to permit the guide wire to pass therethrough, and a channel extending between and aligned with the bores.

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Claims 9, 10, 49, 50 and 62, see column 8, lines 40-43 for device (66) having a metal ribbon (58), and metal is inherently visible under X-ray fluoroscopy.

Claims 11 and 51, see Figure 4 for an elongated introducer (86) having a lumen (88), thereby making it capable of being slidably received on the guide wire proximal to the device.

Claims 15 and 55, see Figure 3 and column 10, lines 54-60 and column 11, lines 18-20 for guide tube (74) having an inner lumen (84).

Claims 64, 65, 68, 69, 71 and 72, see column 8, lines 40-43. The device is configured to be in a straighter deformed configuration while being advanced into the coronary sinus because the nitinol ribbon (58) of the device tends to curve the device. When the device is deployed, it will first naturally curve according to the nitinol ribbon towards (in the direction of) an unstressed shape for the purpose of reshaping the mitral valve annulus.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2, 8, 12, 42, 48 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langberg et al. in view of de Toledo et al. (USPN 4,830,023 as cited in previous office action).

Langberg et al. discloses an assembly for effecting the condition of a mitral valve annulus with all the elements of claims 1 and 41, but is silent to the guide wire being formed of a material

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visible under X-ray fluoroscopy, and the guide wire and introducer being an elongated coil, as required by claims 8, 48 and 2, 12, 42, 52, respectively. de Toledo et al. teaches a metal guide wire (claims 8 and 48) being an elongate coil in order for it to have greater flexibility (claims 2, 12, 42 and 52). See abstract. Because both the guide wire and introducer of Langberg et al. require flexibility to travel through the venous system into to the coronary sinus, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of de Toledo et al. to modify the guide wire so that it is made of metal, and therefore by nature visible under X-ray fluoroscopy, and the guide wire and introducer of Langberg et al. such that they are elongated coils in order for them to have greater flexibility for the travel.

8. Claims 13, 14, 53, 54, 63 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langberg et al. in view of Taylor et al. (2002/0183835 as cited in previous office action).

Langberg et al. discloses an assembly and device for effecting the condition of a mitral valve annulus with all the elements of claims 1, 41, 56 and 57, but is silent to a releasable locking mechanism configured to releasably lock the proximal end of the device to the distal end of the introducer, as required by claims 13, 53, 63 and 67. Taylor et al. teaches an assembly for effecting the condition of a mitral valve annulus and a mitral valve annulus constricting or therapy device that uses a locking mechanism to releasably lock the proximal end (190) of the device to the distal end of the introducer (187) in order for the device to be pulled backward within the coronary sinus, either for positioning or removal purposes. See [0098]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the

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teachings of Taylor et al. to modify the assembly and device of Langberg et al. by adding a releasable locking mechanism to releasably lock the device to the introducer in order to pull the device backwards within the coronary sinus for positioning or removal purposes. Taylor et al. does not disclose expressly that the releasable locking mechanism is a locking pin and a complimentary dented locking groove, as required by claims 14 and 54. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the locking mechanism include a locking pin and complimentary dented locking groove because applicant has not disclosed that pin and groove provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected applicant's invention to perform equally well with the grasper of Taylor et al. or any other attachable interface known in the art because the ability for the device to be repositioned or removed is not affected by the type of releasable locking mechanism used between the device and introducer. Therefore, it would have been an obvious matter of design choice to modify Taylor et al. to obtain the invention as specified in claims 14 and 54.

Allowable Subject Matter

9. Claims 66, 70 and 73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

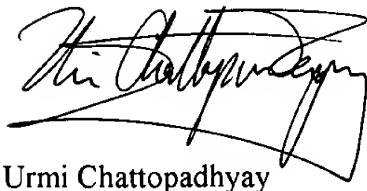
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Response to Arguments

10. Applicant's arguments with respect to claims 1, 2, 4-15, 41, 42 and 44-73 have been considered but are moot in view of the new ground(s) of rejection.

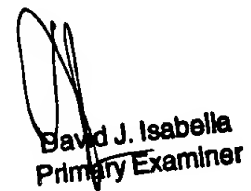
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner